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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/581,398	08/03/2000	ABDESSATAR CHTOUROU	065691/0193	9759

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WASHINGTON, DC 20007

EXAMINER

MOHAMED, ABDEL A

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 03/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/581,398

Applicant(s)

CHTOUROU ET AL.

Examiner

Abdel A. Mohamed

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 December 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 24,25,29,31,33,34,36,37,40-49 and 52 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 24,25,29,31,33,34,36,37,40-43 and 52 is/are allowed.
- 6) ☒ Claim(s) 44-49 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 July 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

ACKNOWLEDGMENT OF AMENDMENT, REMARKS AND STATUS OF THE CLAIMS

1. The amendment, remarks filed on 12/15/04 are acknowledged, entered and considered. In view of Applicant's request claims 24, 29, 31, 40-43 and 46-49 have been amended and claims 32, 39 and 51 have been canceled. Claims 24, 25, 29, 31, 33, 34, 36, 37, 40-49 and 52 are now pending in the application. The objection and the rejections under 35 U.S.C. 112, second paragraph and 35 U.S. C. 103(a) over the prior art of record are withdrawn in view of Applicant's amendment, cancellation of claims and remarks filed 12/15/04. However, the rejection under 35 U.S.C. 112, first paragraph is maintained for the reasons of record.

ARGUMENTS ARE NOT PERSUASIVE

CLAIMS REJECTION-35 U.S.C. § 112 FIRST PARAGRAPH

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 44-49 remain rejected under 35 U.S.C. 112; first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicant's arguments filed 12/15/04 have been fully considered but they are not persuasive. Applicant has argued that the specific activity value of 0.47 IU/mg arrived by the Examiner is not supported by the specification and the Examiner cites no literature reference of how this calculation was derived. The Examiner uses the following formula: $3 \times 113.5 \text{ liters} / 835 \text{ g} = .47 \text{ IU/mg}$. (The Examiner thanks Applicant for pointing out the typographical error. It should be corrected to 0.407 IU/mg).

Applicant continues by stating that specific activity is calculated as follows:

$$3 \text{ IU/ml} \times 1000 \text{ liters} \times 113.5 \text{ liters} = 340,500 \text{ IU}$$

$$340,500 \text{ IU} / 835 \text{ g} = 407.78 \text{ specific activity}$$

A specific activity of 408 is within the recitation of claims 44 and 45. Therefore, the claims are commensurate with the enablement provided by the disclosure is not persuasive. Contrary to Applicant's arguments, the specification teaches on Example 1 the preparation of a factor VIII solution by filtration from a cryoprecipitated fraction of plasma wherein the starting factor VIII solution is carried out in 835 g of cryoprecipitate, representing 113.5 liters of plasma, are redissolved in a solution of heparinized water (3 IU/ml). When one calculates 3×113.5 divided by 835, the result is approximately 0.407 IU/mg (See the correction of typographical error) and not as calculated by Applicant 407.78 specific activity. Note that Applicant's calculation of 407.78 is off by magnitude of 3 because claims 44 and 45 are directed in units of 50 IU/mg and 100 IU/mg, respectively. It appears that Applicant calculated the units in grams rather than milligrams and that is why Applicant is off with three magnitudes. Thus, according to Example 1 in the instant specification, the starting factor VIII solution has a specific

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activity of about 0.407 IU/mg and it is not clear how the starting factor VIII solution has specific activity at least equal to 50 IU/mg or 100 IU/mg as claimed in claims 44 and 45.

Further, Table I, which is purified and filtered factor VIII, has a specific activity of maximum 95 IU/mg, and maximum of protein content of 1.13 mg/ml. respectively.

Therefore, the scope of the claims is not commensurate with the enablement provide by the disclosure with regard to a starting factor VIII solution having a specific activity at least equal to 50 IU/mg or 100 IU/mg or having a concentration from approximately 2 to approximately 100 IU/ml or from approximately 10 to approximately 50 IU/ml or a protein content from approximately 0.05 to approximately 0.5 mg/ml or from approximately 0.1 to approximately 0.5 mg/ml as claimed in claims 44 to 49, respectively.

Thus, the scope of the specific activity, concentration and protein content of the starting factor VIII claimed are very broad and speculative, and as such, it would include those ranges that have not been shown or taught to be useful or enabled by the disclosed method of making and using the invention. Moreover, undue experimentation is necessary to determine under what condition, the claimed invention as broadly claimed in claims 44-49 is enabled, since a wide range of starting factor VIII solution having a specific activity at least equal to 50 IU/mg or 100 IU/mg or having a concentration from approximately 2 to approximately 100 IU/ml or from approximately 10 to approximately 50 IU/ml or a protein content from approximately 0.05 to approximately 0.5 mg/ml or from approximately 0.1 to approximately 0.5 mg/ml are contemplated and are encompassed as well as various situations. The results desired

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appear to be highly dependent on all variables, the relationship of which is not clearly disclosed.

Therefore, without guidance through working example(s), one of ordinary skill in the art would not predict from the protocols disclosed on page 8, lines 18 to 33 in the instant specification to prepare a factor VIII solution, wherein the starting factor VIII solution has specific activities, concentrations and protein contents in the manner claimed in claims 44-49 in the instant invention. Thus, the specification does not enable any person skilled in the art to which it pertains, or which is most nearly connected, to use the invention commensurate in scope with the claims. In the express absence of one or more examples, evidence and sufficient guidance, the skilled artisan would be faced with undue experimentation for practicing the invention.

ACTION IS FINAL

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

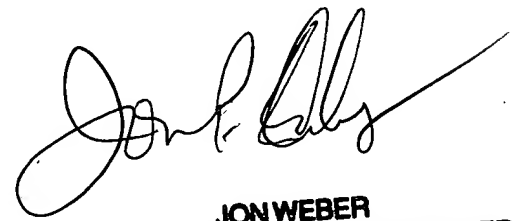
CONCLUSION AND FUTURE CORRESPONDANCE

Claims 24, 25, 29, 31, 33, 34, 36, 37, 40-43 and 52 are allowed and claims 44-49 are rejected.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Abdel A. Mohamed whose telephone number is (571) 272 0955. The examiner can normally be reached on First Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber can be reached on (571) 272 0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



JON WEBER
SUPERVISORY PATENT EXAMINER

 Mohamed/AAM
March 1, 2005